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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

MICHENER, JENNIFER KOLB

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1762 | 6 |

DATE MAILED: 10/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/911,218 | QIU ET AL. |
| | Examiner | Art Unit |
| | Jennifer Kolb Michener | 1762 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 07 August 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-13 and 17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-13 and 17 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) Other: _____

DETAILED ACTION

Specification

1. The previous objection to the disclosure is withdrawn based on Applicant's amendment.

The following new objection is made based on Applicant's amendment:

2. The amendment filed 8/7/2002 is objected to under 35 U.S.C. 132 because it appears to introduce new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. In response to Examiner's previous objection to the disclosure indicating that the formulas described in the specification were not present, Applicant has added numerous formulas to overcome Examiner's objection. However, the added formulaic material does not appear to be supported by the original disclosure. The broad teaching of chemical compounds with a discussion of optional side units thereon, as presented in the original disclosure, does not appear to support the specific formulas required by Applicant's amendment.

If Applicant can provide the location for support of these formulas in the originally-filed specification, this new matter objection will be withdrawn.

Otherwise, Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

3. The objections to claims 1, 7, 8, and 11 have been withdrawn based on Applicant's amendment.

Based on Applicant's amendment, the following new rejection is made:

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-13 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's amendment to claim 1 requires the polyelectrolytic tie layer to be composed of at least a "polyionic material which is not covalently attached to the surface of the article". It does not appear that the originally-filed specification has support for such a limitation. Upon careful reading of the specification, Examiner notes that on page 45, Applicant states that the polyelectrolytic tie layer is "adsorbed onto and/or heteropolarly bound on the surface". While these types of interaction may not be covalent in nature, this teaching on page 45 does not provide support for the broad limitation of "not covalently attached" required by Applicant's amendment. On page 72, Applicant states that the "tie layer is obtainable by grafting one or more....monomers onto the surface". In this instance, it is

Examiner's position that the use of the word "grafting" would be inclusive of, if not equivalent to, covalent attachment, as known in the art.

If Applicant can provide the location for support of the new claim limitation in the originally-filed specification, this new matter rejection will be withdrawn.

Claim Rejections - 35 USC § 102

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1-2, 5-6, and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakagawa et al. (U.S. Pat. 5,409,731).

Examiner maintains the rejection.

8. Claims 1-2, 5-6, and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson (U.S. Pat. 6,050,980).

Examiner maintains the rejection.

9. The rejection of claims 1-3, 5-6, and 12-13 under 35 U.S.C. 102(b) as being anticipated by Takemura et al. (U.S. Pat. 4,876,126) has been withdrawn, based on Applicant's amendment, in favor of inclusion in 103 rejection, below. The rejection of claims 14-15 under the same has necessarily been withdrawn based on Applicant's cancellation of these claims.

10. The rejection of claims 1-4, 6, and 12-13 under 35 U.S.C. 102(b) as being anticipated by Vanderlaan et al (U.S. Pat. 6,087,415) has been withdrawn based on Applicant's amendment in favor of incorporation of these claims in the 103 (a) rejection, below.

The rejection of claim 15 over Vanderlaan has necessarily been withdrawn due to cancellation of the claim.

Claim Rejections - 35 USC § 103

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claims 1-6 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takemura et al.

Examiner maintains the rejection of claim 4 under 103 (a).

Examiner necessarily withdraws the rejection of claim 16 over Takemura, based on Applicant's cancellation of said claim.

Based on Applicant's amendment requiring "non-covalent" attachment of the tie coat, claims 1-3, 5-6, and 12-13 have been included in this 103 (a) rejection for the following reasons:

Takemura et al. teach that which is disclosed in the previous office action regarding the 102 (b) and 103 (a) rejections, specifically the use of a reactive functional group to form an undercoating on the substrate to provide covalent attachment to a subsequently

applied polymer coat, which acts as an "active agent". The reactive groups of Takemura are "polyionic" (see col. 6, lines 44-51). Takemura specifically states:

"...the substrates are pre-treated with substances having a reactive functional group so that the reactive functional group may be present in or on the substrates, and the water-soluble polymer as specified by the present invention is covalently bonded therewith. The form of bond may include covalent bond, ionic bond, physical adsorption, etc. The covalent bond is most preferred in retention, although the ionic bond is allowable."

From the above, it is clear that Takemura is teaching covalent bonding of the polymer (the active agent) to the reactive functional group (the tie coat), but does not mention any requirement of a covalent attachment of the reactive functional group to the substrate.

Regarding Applicant's new requirement that the tie coat be attached to the substrate in a non-covalent manner, Examiner notes that it is not clear from the above passage whether the sentence "The form of bond may include covalent bond, ionic bond, physical adsorption, etc." refers to the bond of polymer to functional group or functional group to substrate. For examination purposes, Examiner assumes that this bond type is referring to the bond of the polymer to the tie coat. Thus, Takemura would be silent with regard to the type of bond used to bond the functional tie coat to the surface. However, it would have been obvious to one of ordinary skill in the art that the tie coat must inherently be attached to the substrate in some manner, either covalently, ionically, or by physi-sorption. Therefore, based on the desired strength of bond, it would have

been obvious to one of ordinary skill in the art to select a type of attachment from among a limited class of attachment types for a given application process. It would have been obvious to one of ordinary skill in the art to use any of either covalent or ionic bonds (chemi-sorption) or physi-sorption (as taught by Takemura as effective bonding methods for other coating layers in the method of his invention) to apply a reactive functional group to a substrate surface with the expectation of reasonable success based on the teachings of Takemura.

Examiner notes that if it became clear that the sentence from the above passage refers specifically to the reactive group bond to the substrate, then the 102(b) rejection would be re-applied.

13. Claims 1-4, 6-13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanderlaan et al.

The rejection of claim 16 has necessarily been withdrawn due to cancellation of the claim.

Claims 1-4, 6, and 12-13 have been incorporated in this 103 (a) rejection due to the new limitation present in Applicant's claim 1.

Vanderlaan teaches that which is disclosed in the 102 and 103 rejections of the previous office action.

Applicant's amendment requires the tie layer be attached to the surface without covalent bonds.

Vanderlaan teaches that the amine or hydroxyl functional monomers or macromers "may be used to incorporate the hydroxyl or amino functionalities into the surface" (col. 2, line 64). Vanderlaan is silent with regard to any further methods used to incorporate said monomers or macromers "into the surface". It is Examiner's position that there are a limited number of ways of achieving this incorporation: these monomers may be bound through the use of ionic or covalent bonds or they may attach through physisorption. The language used by Vanderlaan, such that monomers are "incorporated" "into" the surface does not limit such attachment to covalent bonding. In fact, since Vanderlaan is silent with regards to a bonding mechanism, it is Examiner's position that the monomers of Vanderlaan may be merely adsorbed or anchored "into" the pores of the substrate. Given the limited attachment mechanisms encompassed by the phrase "incorporated... into the surface", it is Examiner's position that one of ordinary skill in the art would have selected physi-sorption or ionic bonding from the small class of attachment mechanisms with the expectation of successful operation of Vanderlaan's method in the absence of a showing of criticality. Incorporation into the pores of Vanderlaan's device would provide a fairly stable surface of reactive groups suitable for subsequent attachment of the hydrophilic and antimicrobial coatings.

Regarding new claim 17, it is Examiner's position that dipping and spraying are commonly used methods of applying coatings and are considered interchangeable by one of ordinary skill in the art, absent a showing of criticality. While potentially less cost-effective, it would have been obvious to one of ordinary skill in the art to apply one tie

layer by spraying and one by dipping, as required by Applicant, with the expectation of similar, successful results because both application methods provide uniform coatings.

14. The rejection of claim 14 under 35 U.S.C. 103(a) as being unpatentable over Vanderlaan et al. in view of Takemura has been withdrawn due to cancellation of the claim.

Response to Arguments

15. Applicant's arguments filed 8/7/2002 have been fully considered but they are not persuasive.

Applicant argues that Nakagawa fails to teach covalent attachment of the tie layer to the surface or the use of a polyionic material to functionalize the surface in a non-covalent manner.

Examiner notes that the amino group-containing tie layer of Nakagawa is polyionic (see Example 3, line 6) and is also merely "adsorbed" to the surface (col. 6, line 45), which would meet Applicant's requirement of "not covalent".

Applicant argues that Wilson does not use a polyionic material, nor is such a material attached to the substrate in a non-covalent manner.

Examiner argues that the polydiisocyanate of Wilson is a polyionic material. As the name implies, there are a plurality of cyanates in the chemical of Wilson. Furthermore, the cyano group is ionic in nature. Regarding the non-covalent attachment, Examiner

notes that Wilson does not specifically teach whether the coating of the polydiisocyanate is covalently attached, but Wilson does teach that the same type of tie coat is provided in other patents, such as 4,378,803, in which Takagi teaches that the diisocyanate tie coat may be either covalently attached to the substrate or attached by adsorption. Since Wilson incorporates Takagi and Takagi teaches that the same type of coating may be adsorbed, the Wilson reference meets Applicant's new limitation.

Applicant argues that Takemura teaches covalent attachment of the water-soluble polymers to the substrate, which is counter to the new limitation in claim 1.

Examiner disagrees. Takemura teaches covalent attachment of these polymers to the reactive underlayer (tie coat), not to the substrate, as outlined in the rejection above. The reactive underlayer tie coat may be applied in a non-covalent manner, for those reasons outlined above.

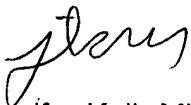
It is believed that Applicant's arguments regarding the Vanderlaan reference have been addressed in the rejection, above.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.


Jennifer Kolb Michener
October 16, 2002


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